K120305

JUL 9 2012

510(k) Safety and Effectiveness Summary

ThinkingNet Modality Applications and Web Extensions

1.1 Demographic Information

1.1.1 Date Prepared

January 15, 2012 (Last update on July 5, 2012)

1.1.2 Submitter

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1.1.3 Contact

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1.2 Device Name

ThinkingNet Modality and Web Applications

1.2.1 Trade or Proprietary Names

ThinkingPACS/RIS (same as ThinkingNet), ModalityBroker (when used as a modality PACS), ThinkingArchive (the image archival and management subsystem), MDStation (the image review and processing subsystem), NuGateway (the image connectivity subsystem) and ThinkingWeb (the remote Web access subsystem).

1.2.2 Common Name

The common name used by FDA for similar devices is **Picture Archive and Communications System (PACS)**.

1.3 Classification(s) of the Device

When the software modules are packaged and marketed as an image storage and communications device, with just NuPAX and NuLink (NuGateway) only for example, the system

falls in the classification of **Medical Image Storage** (Section 892.2010, product code LMB) and **Medical Image Communications** (Section 892.2020, product code LMD) devices. They are Class I.

As an integrated product, **ThinkingNet** with software modules that provide functions for advanced image processing, manipulation, enhancement, compression or quantification, is classified as a **Picture Archiving and Communications System** (PACS, Section 892.2050). The classification panel is **Radiology** and the product code is **LLZ**. It is a Class II device.

1.4 Device Description

ThinkingNet is a multi-modality PACS/RIS with applications optimized for each individual imaging modality. The image data and applications can be accessed locally or remotely. ***ThinkingNet*** workstation software is designed as diagnostic reading and processing software packages, which may be marketed as software only, as well as packaged with standard off-the-shelf computer hardware.

The base functions include receiving, transmission, storage, archival, display images from all imaging modalities. When enabled, the system allows remote access of image data and applications over a local or wide area network, using a Web browser, thick-client, thin-client or cloud-based remote application deployment method.

Options allow for additional capability, including modality specific applications, quantitative post-processing, modality specific measurements, multi-planar reformatting and 3D visualization.

ThinkingNet ***Molecular Imaging*** modules offer the image processing functionality, through MDStation and ThinkingWeb, that have the same indication as the predicate modality workstations. It delivers image processing and review tools for applications used in functional imaging modalities, such as nuclear medicine, PET, PET/CT, SPECT/CT and PET/MRI.

ThinkingNet ***Mammo*** module is a diagnostic softcopy breast imaging workstation with diagnostic print capability.

- It displays and prints regionally approved DICOM DR Digital Mammography Images (MG SOP class) with a default or user defined mammography hanging protocol.
- It displays and prints regionally approved DICOM CR Digital Mammography Images (CR SOP class) a default or user defined mammography hanging protocol.
- It displays adjunct breast imaging modality studies (i.e. Breast MR, Breast US, Breast PET and Breast gamma camera) for comparison.

ThinkingWeb modules offer comprehensive remote image and application access methods to allow clinicians to review and process images remotely. It has the following modules.

- ThinkingWebLite: Clientless image distribution via simple Web browser (see NuWEB in K010271). It is primarily a referral physician's portal, not intended for primary reading.
- ThinkingNet.Net: A thick-client implementation using an existing image review module (NuFILM) with a proprietary image streaming mechanism.
- ThinkingWeb: Cross-platform thin-client remote application access based the existing MDStation software and off-the-shelf remote computing technology.
- ThinkingWeb Extreme: A cloud-based remote application deployment implementation based the existing MDStation software and off-the-shelf cloud computing technologies.

Besides ThinkingNet.Net, all ThinkingWeb products support cross-platform client computer devices. Thinking.Net uses Windows-based client computer.

1.5 Intended Use

ThinkingNet with its modality specific and remote access applications is intended to be used by trained clinical staff to perform medical image management, communications, archiving and processing and review of medical images.

The system can run on dedicated workstation or in a server-client configuration.

1.6 Description of Changes

Since we claim that ThinkingNet is optimized for each individual imaging modality, we feel that is appropriate to make ThinkingNet functionally comparable with modality workstations manufactured by modality vendors. In this application we will compare ThinkingNet imaging modality specific applications in radiology, cardiology, molecular imaging and mammographic imaging modalities with modality specific predicate devices and applications.

As the computer software and IT technologies evolve, a Web-based thin and thick client solution can deliver the same user interface, functionality and speed as a dedicated full diagnostic workstation. The proposed change also involves the expansion of ThinkingWeb (previously cleared as NuWEB in K010271) to include full workstation featured remote viewing and processing functions. The client device is cross-platform except for the ThinkingNet.Net thick-client solution.

These changes have been a part of the natural evolution of ThinkingNet without requiring major design changes. The product remains as safe and effective as the previously cleared ThinkingNet (K010271) and the predicate devices.

1.7 Legally Marketed Predicate Devices

Thinking Systems *ThinkingNet* is substantially equivalent to following primary predicate devices.

Device Name	**FDA Clearance Number**	**Primary Indications**
Philips/Stentor iSite PACS 4.x and iSite Radiology	K063267, K013630 (primary predicate)	Web-based Multi-modality PACS and PACS Workstation
Thinking Systems ThinkingNet	K010271	All

Thinking Systems *ThinkingNet* is substantially equivalent to following additional predicate devices in the respective specific indications.

Device Name	**FDA Clearance Number**	**Specific Indications**

GE Xeleris 3	K093982	Nuclear medicine, multi-modality image co-registration and fusion, PET-CT, SPECT-CT and CT image processing, integrated third-party post-processing software, such as Cedars QGS/QPS/QBS, Invia 4D MSPECT, Syntermed ECTb and Syntermed NeuroQ
Agfa/Heartlab Ascentia	K050228	Cardiology PACS
Agfa IMPAX MA3000	K081976	Mammography review
GE EchoPAC	K101324	Echocardiography and vascular image review, measurements and calculation
GE AW Server	K081985	RECIST, Quantitative oncology response assessment

1.8 Determination of Substantial Equivalence

ThinkingNet with its Web options and modality specific modules has the same intended use and indications for use, target populations, and technical characteristics as the legally marketed predicate devices in the respective areas tabulated above. Specifically,

- **ThinkingNet** with ThinkingWeb options is a medical image management, communications and review device that has the same indications for use, target populations and technical characteristics as the legally marketed predicate device Philips iSite PACS with iSite Radiology client (K063267, K013630) and ThinkingNet (K010271). They are substantially equivalent.

  The main difference between ThinkingNet and Philips iSite are the following.
  1. ThinkingNet contains more inherently built-in modality specific applications. iSite offers many modality specific applications via internal and 3rd-party integration of plug-ins or add-ons.
  2. ThinkingWeb Extreme and ThinkingWeb use server-side processing and do not download any patient data. iSite client on the other hand uses an image streaming technology to download image data onto the client device.
  3. ThinkingWeb Extreme and ThinkingWeb support both Windows and non-Windows client devices. iSite is Windows specific.

- **ThinkingNet** molecular imaging subsystem is substantially equivalent to GE Xeleris (K093982). Note: GE Xeleris Suite is also marketed as part of GE Centricity PACS in addition to being a workstation.

- **ThinkingNet** mammography imaging module is substantially equivalent to Agfa IMPAX MA3000 (K081976). It can be used for screening and diagnosis (with MG, "For presentation" images only) from FDA approved modalities in softcopy (using FDA cleared displays for mammography) and printed formats.

- **ThinkingNet** cardiology subsystem is substantially equivalent to Agfa/Heartlab Ascentia (K050228).

- **ThinkingNet** RECIST module for solid tumor treatment response evaluation is substantially equivalent to GE AW Server's OncoQuant subsystem.

- **ThinkingNet** NuFILM's echocardiography image review, measurement and calculation module is substantially equivalent to GE EchoPac (K101324). The main difference is that NuFILM is more vendor neutral because it does not rely on proprietary files native to GE echo machines.

The differences between the ThinkingNet software and the predicate devices may affect the safety and effectiveness of the device. Performance testing was conducted to show that ThinkingNet is safe and effective.

ThinkingNet is designed, developed, verified and validated following Thinking Systems' ISO 13485 registered and FDA 21 CFR Part 820 compliant Quality System.

The following quality assurance measures were applied to the development of the system.

- Requirements Specification
- Design Specification
- Hazard and Risk Analysis
- Modular Testing
- Verification Testing
- Validation Testing (Performance Testing)
- Integration Testing

1.9 Conclusion

Thinking Systems considers ThinkingNet with its Web options and modality specific modules to be as safe, as effective, and performance is substantially equivalent to the predicate device(s) listed in Section 1.7.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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JUL 9 2012

Re: K120305
Trade/Device Name: ThinkingNet Modality and Web Applications
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 31, 2012
Received: June 13, 2012

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

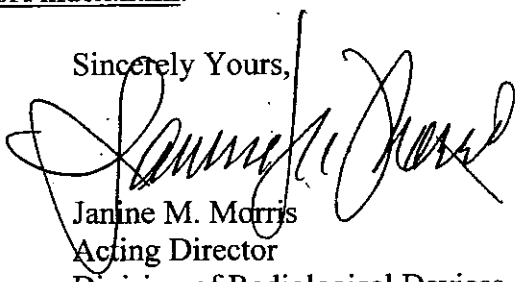
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known): K120305

Device Name: ThinkingNet Modality and Web Applications

Indications For Use:

The **ThinkingNet** is a **Medical Image Management and Review System**, commonly known as PACS. **ThinkingNet** made by Thinking Systems Corporation, Florida, USA, is indicated for acceptance, transmission, storage, archival, reading, interpretation, clinical review, analysis, annotation, distribution, printing, editing and processing of digital images and data acquired from DICOM compatible diagnostic device, by healthcare professionals, including radiologists, cardiologists, physicians, technologists and clinicians.

- With a ThinkingWeb option it can be used to access diagnostic information remotely with all workstation functionality or to collaborate with other users. The client device is cross platform for all but the thick-client ThinkingNet.Net option.
- With the molecular imaging option it can be used for processing and interpreting nuclear medicine and other molecular imaging studies.
- With image co-registration and fusion option it can be used for processing and interpreting PET-CT, PET-MRI, SPECT-CT and other hybrid imaging studies.
- With the Mammography option it can be used for screening and diagnosis (with MG, "For presentation" images only) from FDA approved modalities in softcopy (using FDA cleared displays for mammography) and printed formats.
- With the cardiology option it can be used for reading, interpreting and reporting cardiac studies, such as nuclear cardiac, PET cardiac, echocardiographic, X-ray angiographic and CTA studies.
- With the Orthopedic option it can be used to perform common orthopedic measurements of the hip, knee, spine, etc.
- With the 3D/MPR option it can be used to volumetric image data visualization: MIP, MPR, VR and triangulation.
- With the Quality Assurance option it can be used by PACS administrators or clinicians to perform quality control activities related to patient and images data.

Prescription Use X OR Over-The-Counter User _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K120305

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